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Phoenix, Arizona 85007

JOHN A. LASOTA, JR.
ATTORNEY GENERAL

July 11, 1978

Alexander Kelter, M.D.
Assistant Director
Division of Disease Control Services
Department of Health Services
1740 West Adams
Phoenix, Arizona 85007

Re: 78-140 (R77-391)

Dear Doctor Kelter:

This opinion is in answer to your letter of December 7, 1977 where you requested advice on the following matters:

1. Can the requirements of A.R.S. § 36-405.01(A)(4)(5), Health screening services, be reconciled with § 36-470(A)(B), Clinical laboratories?

2. Do A.R.S. §§ 36-470(A) and 36-470(B) permit attorneys to request the collection of laboratory specimens and use the findings of laboratory examinations?

3. Does Chapter 25 of the Session Laws 1977, formerly § 36-402.5, Exemptions, and the present § 36-402 exempt transfusion services and hospital laboratories from regulation by the Department of Health Services?

We respond as follows:

I.

A.R.S. § 36-405.01(A)(4), Health screening services, states that "individuals may obtain health screening services on their own initiative" while § 36-405.01(A)(5) requires that data given to these individuals must be "properly informative and not misleading." The relevant portion of § 36-470(A) obliges clinical laboratories to perform examinations at the request of physicians authorized to practice medicine and surgery or by persons permitted by law to use the findings of laboratory examinations. Section 36-470(B) compels the laboratory to report its findings to the physician or other authorized persons. Failure of a licensed laboratory to observe this requirement is grounds for loss of its license (A.R.S. § 36-473.4) and for a criminal penalty (A.R.S. § 36-479.A.4).

Two questions must be answered in reconciling A.R.S. § 36-405.01(A)(5) and A.R.S. § 36-470(A)(B). First, are individuals who obtain health screening services on their own initiative pursuant to § 36-405.01(A)(4), permitted by § 36-470(A) to request laboratory examinations and to receive the results by § 36-470(B)? Second, if these individuals are not within the two authorization clauses of § 36-470(A)(B), is it possible to reconcile § 36-405.01(A)(4)(5) and § 36-470(A)(B)?

A.

It is unlikely that the legislature intended § 36-405.01(A)(4) to authorize laymen to request clinical laboratory examinations and their results. Section 36-470(A) allows "persons permitted by law to use the findings of laboratory examinations" to order these tests. Section 36-470(B) states that an "authorized person" may request the results. As a general rule "to permit" or "to authorize" are synonymous. State v. Laven, 270 Wis. 524, 71 N.W.2d 287 (1955). To be authorized or permitted by law means to be endowed with authority; it is an affirmative grant of authority. Doherty v. Kansas City Star Co., 143 Kan. 802, 57 P.2d 43 (1936).

Significantly, § 36-405.01(A)(4) does not authorize laymen to order clinical laboratory tests. It simply states that individuals may obtain health screening services at their own initiative. In order to understand the implications of § 36-405.01(A)(4) and its relationship to the other health statutes it is first necessary to examine § 36-405.01 in its entirety to determine the purpose of the new health screening statute. See Coggins v. Ely, 23 Ariz. 155, 202 P. 391 (1921); State v. Vondohlen, 24 Ariz.App. 362, 538 P.2d 1163 (1975).

An examination of § 36-401(12), Definitions, and § 36-405.01, Health screening services, indicates that the intent of the legislature in enacting the latter statute was to provide the consumer with an alternative to the physician's private office for determining whether he is in need of medical treatment. A.R.S. § 36-401(12) as amended Chapter 172, § 4, Session Laws 1977, defines health screening services as

> . . . the acquisition, analysis and delivery of health-related data of individuals for the purpose of aiding in the determination of the need for medical services.

and A.R.S. § 36-405.01, Health screening services, states:

> A. Health screening services shall be conducted in the following manner:
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> 1. Health screening services shall be conducted under the direction of or, when required by good medical practice, under the supervision of a physician.
>
> 2. Any diagnosis of collected health-related data shall be performed by a physicican.
>
> 3. Any examination of secretions, body fluids or excretions of the human body shall be performed pursuant to title 36, chapter 4.1.
>
> 4. Individuals may obtain health screening services on their own initiative.
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> 5. Data given health-screened individuals shall be properly informative and not misleading.
>
> . . .
>
> 7. A patient who is in need of medical care shall be informed that he should see a physician without referral to any particular physician.

A health screening agency as described in A.R.S. § 36-401 and § 36-405.01 is a health-related service entity designed to detect health problems in individuals and to refer them to physicians for appropriate treatment. Section 36-405(A)(4)'s statement that an individual may obtain health screening services simply affirms the person's right to seek these preliminary screening services without the approval of a physician. However, the need for more extensive clinical tests is to be determined by a physician on the basis of what the initial health screening procedures indicate.

Support for this interpretation of § 36-405.01(A)(4) is found in § 36-405.01(A)(3) which indicates that clinical laboratory examinations must be conducted in accordance with the clinical laboratory statutes, including § 36-470(A)(B). If the legislature had intended to bring laymen within the authorization clauses of § 36-470(A)(B), permitting them to request the collection of laboratory specimens and the use of laboratory examination findings, it would have made a

clear affirmative grant of this authority in § 36-405.01(A)(3). Section 36-405.01(A)(4) does not conflict with § 36-470(A)(B) and can be reconciled with the latter statute.

B.

Having reconciled § 36-405.01(A)(4) with § 36-470(A)(B) we must determine whether § 36-405.01(A)(5) conflicts with the latter statute. Section 36-405.01(A)(5) requires that data given health screened individuals "be properly informative and not misleading." This limitation must be read in conjunction with § 36-405.01(A)(1),(2) and (3) which require that health screening services be conducted under the direction of a physician, that any diagnosis based on health related data be done by a physician and that all examinations of secretions, bodily fuilds or excretions of the human body be performed pursuant to Chapter 4.1, the clinical laboratory licensing statutes. Further, § 36-470(B) of Chapter 4.1 does not permit a clinical interpretation, diagnosis or prognosis to appear on the laboratory report and restricts the reporting of the results to the physicians who requested them.

Construed together §§ 36-405.01(A)(1), (2), (3), (5) and 36-470(B) indicate that test results cannot be given to a patient without their first having been examined by a physician who will interpret the findings for the patient and (with or without a clinical evaluation) give the indicated diagnosis. Without such an interpretation the examination report would probably be meaningless to a layman and would not meet the § 36-405.01(A)(5) requirement that data be properly informative and not misleading. Failure to meet this standard would partially invalidate § 36-405.01 and defeat its legislative purpose. Statutes are to be given a sensible construction such as will accomplish the legislative intent and if possible should avoid absurd conclusions that would invalidate them. State ex rel. Flournoy v. Mangum, 113 Ariz. 151, 548 P.2d 1148 (1976); Arizona Tax Commission v. Reiser, 109 Ariz. 473, 512 P.2d 16 (1973); State v. Airesearch Mfg. Co., Inc., 68 Ariz. 342, 206 P.2d 562 (1949).

II.

You have also asked whether A.R.S. § 36-470(A) and (B) provide authority for attorneys to order the collection of laboratory specimens and use the findings of laboratory examinations. As noted above, A.R.S. § 36-470(A) states that only a physician authorized to practice medicine or another person permitted by law to use the findings of clinical laboratory examinations may request those examinations. To authorize or be permitted by law requires an affirmative grant of authority by the legislature. See Landry v. Dailey, supra; Doherty v. Kansas City Star Co., supra.

An examination of the relevant Arizona statutes reveals that the legislature has not granted attorneys the authority to request clinical laboratory examinations or their findings. Nor could a physician delegate his authority to order these procedures to an attorney. Such a transfer of authority can occur only where the delegation is to another physician or someone otherwise empowered to order laboratory tests. Op.Atty.Gen. 75-127. Therefore attorneys may neither order the collection of laboratory specimens nor use the findings of laboratory examinations on the basis of A.R.S. § 36-470(A) and (B). We do not address the issue of attorney access to laboratory information pursuant to other provisions of law.

III.

A more difficult question is whether the version of A.R.S. § 36-402 adopted by Chapter 172, Laws of 1977, exempts hospital transfusion services from regulation by the Department of Health Services. Section 36-402(5) adopted by Chapter 25, Laws of 1977 and effective April 27, 1977, exempted the "collection, processing or distribution of whole human blood, blood components, plasma, blood fractions or derivatives procured, processed or distributed by federally licensed and regulated blood banks" from state licensing laws. The Chapter 172, Laws of 1977, version of § 36-402 became effective on January 1, 1978. This version of § 36-402 does not include the federal blood bank exemption. Examination of the session laws indicates that neither statute was designed to repeal or amend the other. The two statutes were probably not blended for printing purposes, because of the difference in effective dates. The legislature undoubtedly intended the two versions of the statute to complement each other and eventually be consolidated. Where statutes control the same subject matter and the latter one does not expressly repeal the former, they should be construed so as to give effect to each, if possible, especially where they are adopted at the same legislative session. State v. Jaastad, 43 Ariz. 458, 32 P.2d 799 (1934).

Having concluded that § 36-402(5) is effective law, we turn to the problem of the exemption's scope and enforceability. In determining whether the legislature intended to exempt hospital blood transfusion services from regulation by the Department of Health Services, it is necessary to begin with an examination of the statutory exemption. Although the question is not free from doubt, a careful reading of the exemption suggests that the legislature probably intended to preclude state inspection of freestanding blood banks and other establishments that manufacture or distribute blood or blood products, but not hospital transfusion services. A review of the applicable federal regulatory structure confirms this statutory interpretation.

Federal law compels any manufacturer and certain distributors of blood or blood products to register their activities with the Food and Drug Administration. 21 C.F.R. 607. Those individuals who manufacture or distribute blood or blood products for commercial purposes are also controlled by federal licensure regulations which state that an entity so engaged must have separate licenses for its establishment and its products. 21 C.F.R. 601. However, facilities such as hospitals, which "manufacture" blood or blood products only for their own use, need not be licensed although they must be registered. Facilities which purchase their transfusion supplies and are not engaged in the manufacturing process are exempt from both registration and licensing.

Individuals or organizations licensed under 21 C.F.R. 601 are regularly subjected to thorough and rigorous inspection by the Food and Drug Administration to determine whether they meet applicable federal manufacturing and product standards. In contrast, registration inspections conducted pursuant to 21 C.F.R. 607 are not as wide ranging or extensive as inspections administered under the federal licensing regulations. While the registration inspectors may examine the equipment and manufacturing process of a hospital's transfusion service, the examination, unlike that of a federal licensing inspection, is mainly concerned with whether the information listed on the registration forms is accurate and current. We must assume that the legislature was aware of this distinction and only intended to exempt free-standing blood banks, which are subject to the strict federal licensing program.

We indicated in Op.Atty.Gen. 70-12, that a clinical laboratory is exempt from state licensing where it is subject to federal licensing programs or to a set of inspection criteria recognized by the federal government as equal to or more stringent that the federal standards. See id. Where a laboratory is not subject to a federal licensing program or a federally recognized equivalent, that laboratory is not exempt from the state licensing program. See Op.Atty. Gen. 76-194. An analogous situation is presented here. Since the registration program is not the equivalent of the federal licensing system, the problem of hospital transfusion services mandates a result similar to that applied to clinical laboratories which are not within the federal

licensing structure. Section 36-402(5) is intended to exempt only those facilities which are both federally licensed and regulated; it does not apply to hospital transfusion services, which are subject only to federal registration.

Very truly yours,

JOHN A. LASOTA, JR.
Attorney General

JAL:kk

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Robert K. Corbin

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findings of laboratory examinations. Section 36-470(B) compels the laboratory to report its findings to the physician or other authorized persons. Failure of a licensed laboratory to observe this requirement is grounds for loss of its license (A.R.S. § 36-473(4)) and for a criminal penalty (A.R.S. § 36-479(A)(4)).

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A. It is unlikely that the legislature intended § 36-405.01(A)(4) to authorize laymen to request clinical laboratory examinations and their results. Section 36-470(A) allows "persons permitted by law to use the findings of laboratory examinations" to order these tests. Section 36-470(B) states that an "authorized person" may request the results. As a general rule "to permit" "to authorize" are synonymous. State v. Laven, 270 Wis. 524, 71 N.W. 2d 287 (1955). To be authorized or permitted by law means to be endowed with authority; it is an affirmative grant of authority. Doherty v. Kansas City Star Co., 143 Kan. 802, 57 P.2d 43 (1936).

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B. Having reconciled § 36-405.01(A)(4) with § 36-470(A)(B) we must determine whether § 36-405.01(A)(5) conflicts with the latter statute. Section 36-405.01(A)(5) requires that data given health screened individuals "be properly informative and not misleading." This limitation must be read in conjunction with § 36-405.01(A)(1), (2) and (3) which require that health screening services be conducted under the direction of a physician, that any diagnosis based on health related data be done by a physician and that all examinations of secretions, bodily fluids or excretions of the human body be performed pursuant to Chapter 4.1, the clinical laboratory licensing statutes. Further, § 36-470(B) of Chapter 4.1 does not permit a clinical interpretation, diagnosis or prognosis to appear on the laboratory report and restricts the reporting of the results to the physicians who requested them.

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III. A more difficult question is whether the version of A.R.S. § 36-402 adopted by Chapter 172, Laws of 1977, exempts hospital transfusion services from regulation by the Department of Health Services. Section 36-402(5) adopted by Chapter 25, Laws of 1977 and effective April 27, 1977, exempted the "collection,processing or distribution of whole human blood, blood components, plasma, blood fractions or derivatives procured, processed or distributed by federally licensed and regulated blood banks" from state licensing laws. The Chapter 172,Laws of 1977, version of § 36-402 became effective on January 1, 1978. This version of § 36-402 does not include the federal blood bank exemption. Examination of the session laws indicates that neither statute was designed to repeal or amend the other. The two statutes were probably not blended for printing purposes, because of the difference in effective dates. The legislature undoubtedly intended the two versions of the statute to complement each other and eventually be consolidated. Where statutes control the same subject matter and the latter one does not expressly repeal the former, they should be construed so as to give effect to each, if possible,

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Sincerely,

John A. LaSota, Jr.,
Attorney General